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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,256	08/20/2003	David H.A. Jones	2578-6077US	6153

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TRASKBRITT, P.C.
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
03/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/644,256	JONES ET AL.	
	Examiner	Art Unit	
	Michele K. Joike	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-12,14-20,22 and 23* is/are pending in the application.

4a) Of the above claim(s) *12 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-11, 22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed August 21, 2009. Claims 1, 6-12, 14-20, 22 and 23 are pending, with claims 1, 6-11, 22 and 23 examined.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Specification

The disclosure is objected to because of the following informalities: Applicant's amendment to the specification is objected to because Applicant's change in claim to priority to include PCT International Application No. PCT/EP03/007690, PCT International Application No. PCT/EP03/50201, European Patent Application No. 02077953.4 and US Provisional Patent Application Serial No. 60/397,066 has not been granted (see below).

Appropriate correction is required.

Priority

The foreign priority claim filed on November 20, 2006 was not entered because the foreign priority claim was not filed during the time period set forth in 37 CFR 1.55(a)(1). For original applications filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the time period is during the pendency of

the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. For applications that have entered national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT. See 37 CFR 1.55(a)(1)(ii). If applicant desires priority under 35 U.S.C. 119(a)-(d), (f) or 365(a) based upon a prior foreign application, applicant must file a petition for an unintentionally delayed priority claim (37 CFR 1.55(c)). The petition must be accompanied by (1) the claim (i.e., the claim required by 35 U.S.C. 119(a)-(d) and (f) and 37 CFR 1.55) for priority to the prior foreign application, unless previously submitted; (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.55(a)(1) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Oath/Declaration

Applicant's declaration which includes a foreign priority claim and which was submitted 11/20/2006 is acknowledged. Although the new declaration identifies the foreign application for patent or inventor's certificate on which priority has been claimed,

such a claim has not been made pursuant to 37 CFR 1.55, and as such is without effect.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for a predetermined amount of time. There is support for various, specified times, but for a predetermined amount of time. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "predetermined amount of time" is vague. It does not give any reference to an amount of time, i.e., there are no lower or upper limits. It is unclear how short or how long the time can be.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6 and 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al (US 6,821,512) in view of Hateboer et al (WO 00/63403, cited by applicants). New claims 22 and 23 are added.

Gao et al (columns 1-2, 7 and 10) teach a PER.C6 cell transfected with a vector encoding an IgA molecule. The IgA molecule can be a human IgA. However, they do not teach the IgA molecule integrated into the cell's genome. Gao et al are also silent about whether the IgA molecule is amplified in the cell. Since there is no teaching in Gao about amplifying the molecule, it is assumed, absent evidence to the contrary, that that the IgA molecule is not amplified in the cell.

Hateboer et al taught a method of producing recombinant proteins in human cells, with particular regards to the field of monoclonal antibody production (pg 1, lines 1-8). Hateboer et al contemplate the use of PER.C6 cells, deposited at the ECACC under #96022940 (pg 7, line 20), to express humanized antibodies (pgs 11-20), and disclose that the PER.C6 cells may express one or more nucleic acids encoding a heavy chain, a variable heavy chain, a light chain and/or a variable light chain of an immunoglobulin, or a functional derivative, homologue and/or fragment thereof (pg 18,

lines 4-8). One type of antibody disclosed is to the EPCAM antigen (page 14). Hateboer et al disclose a working example wherein the PER.C6 cells express humanized monoclonal antibodies (pgs 57-67). Per.C6 cells are immortal cells, and in Ex. 7, the cells are grown for 4-5 weeks. It is assumed that they maintain expression of E1A and E1B, since it is the E1 genes that confer immortality. Applicants also teach in their specification in Ex. 2 that Per.C6 cells were cultured for up to 3 weeks, however, they do discuss expression of E1A or E1B. However, since Per.C6 cells contain E1A and E1B, and the cells are intact and viable, it is assumed that E1A and E1B are expressed in this instance like in the Hateboer reference.

It would have been obvious to one of ordinary skill in the art to integrate the IgA molecule, because Hateboer et al teach that integration can lead to stability for expression and production. An artisan would be motivated to produce IgA in PER.C6 cells because Hateboer et al suggest that PER.C6 cells are advantageous for having been documented extensively, behaving significantly better in the process of upscaling, suspension growth and growth factor independence, e.g. bioreactor growth to very high densities suitable for large scale production. PER.C6 cells have the additional advantage that they can be cultured in the absence of animal- or human-derived serum or serum components. Thus, isolation of the artisan-desired protein is easier, while the safety is enhanced due to the absence of additional proteins (pg 7, lines 20-37 of Hateboer et al).

Furthermore, because most commercially attractive proteins are human, it is advantageous to use a human cell to produce said protein, because human cells, e.g.

PER.C6, would have the advantage of post-translationally modifying, e.g. glycosylating, the immunoglobulin as per the human physiology, wherein the presence of carbohydrates can be critical for antigen clearance functions and antibody activity. PER.C6 cells are advantageous for providing reliable and consistent glycosylation patterns on an antibody by removing the cell type variable and having simplified cell culture conditions that can negatively impact antibody glycosylation patterns (pg 5, lines 9-17; pg 15, lines 20 of Hateboer et al).

Response to Arguments

Applicants have argued that the petition for acceptance of unintentionally delayed priority claims will obviate the objections to the specification and the oath, however, the petition was dismissed. Applicants also argue that 35 U.S.C. 103(a) rejection is improper due to the priority claims of 09/549,463, now U.S. 6,855,544, and 60/129,452, however, there is no support for a cell comprising a recombinant nucleic acid encoding an IgA molecule in either reference. Therefore, Applicants are awarded the filing date of August 20, 2003 as their priority date.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6 and 7 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6-7 and 9 of U.S. Patent No. 7,429,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '486 patent recite producing IgA in PER.C6 cells.

Claims 1, 6 and 7 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 5-7 of U.S. Patent No. 7,262,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '028 patent recite a method for producing IgA (amongst other immunoglobulins) in PER.C6 cells.

Claims 1, 6, 7, 22 and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58, 59, 63-66 of copending Application No. 12/291,881 in view of Gao et al. Claims 58, 59, 63-66 of

application 12/291,881 claim a process for producing a protein of interest in cell ECACC #96022940, wherein the protein of interest can be an antibody. Gao et al (columns 1-2, 7 and 10) teach a PER.C6 cell transfected with a vector encoding an IgA molecule. The IgA molecule can be a human IgA. As noted by Gao et al, IgA is a useful protein in cellular immunity.

This is a provisional obviousness-type double patenting rejection.

Applicants have requested that the ODP rejections be held in abeyance.

Allowable Subject Matter

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/
Primary Examiner, Art Unit 1636

Michele K. Joike
Primary Examiner
Art Unit 1636